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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,444	01/29/2002	Wilhelm Hoerrmann	P67254US0	4260

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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,444

Applicant(s)

HOERRMANN, WILHELM

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Objections

1. Claims 1-3 are objected to because of the following informalities: "Laboratory test" should read "A Laboratory test". Appropriate correction is required.
2. Claims 1-15 are objected to because of the following informalities: "Process" should read "A process". Appropriate correction is required.
3. Claim 16 is objected to because of the following informalities: "Analysis kit" should read "An analysis kit". Appropriate correction is required.
4. Claims 17-19 are objected to because of the following informalities: "Analysis kit" should read "The analysis kit". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claims 1-3, recite "Laboratory test of a body fluid or tissue sample" is vague because it is not clear whether this test consist of an assay method.
8. Claim 3, recite "other corresponding antibody methods" in line 4, is vague because it is unclear as to what these methods refer too.

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9. Claim 4, recite "the body fluid or tissue sample to be analyzed is prepared to eliminate disturbing substances" is vague because it is unclear as to how the body fluid or tissue sample is being prepared.
10. Claim 7, recites the "the mixture" in line 4, lacks antecedent basis; In lines 5, 8 and 9 "the product" lacks antecedent basis.
11. Claim 7, recites "cis-4-hydroxyproline and its derivative content is determined in the product obtained in step d" is unclear because step "d" does not explain how the content is determined.
12. Claim 13, recites "the quantitative analysis" in line 1, lack antecedent basis.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sessa et al (Journal of chromatography, 382(1986) 258-263).

Sessa et al anticipates the instant claims in teaching methods to quantify various isomers (derivatives) of hydroxyprolines in body fluid such as urine and plasma through ion-exchange and chromatography pg. 258, paragraphs 1-3). Particular hydroxyprolines reagents used in the instant method are cis-4-hydroxy-L-proline (c-Hyp), trans-4-hydroxy-L-proline, L-proline and others (pg. 259, paragraph 1). The

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sample that was analyzed was pretreated to allow for sensitive fluorometric detection (eliminate disturbing substances), which is an approach, used to assay hydroxyproline in a sample and purified standards (pg. 258, paragraphs 1-3).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sessa et al (Journal of chromatography, 382(1986) 258-263).

The teaches of Sessa et al are set forth above and differ from the instant claims in not pointing out the sequential steps in the process of to determine cis-4-hydroxyproline and a kit to perform the instant process.

However, Sessa et al teaches the reagents in remaining dependent claims which are either specifically described by the references (e.g. detecting cis-4-hydroxyproline, adding an internal standard and hydrolyzing the sample, adding potassium hydroxide, potassium tetraborate and a derivatizing agent used to pretreated the sample to increase sensitivity (eliminate disturbing substances) (claims 7-10) (see pgs. 259-260, reagents and sample preparation, paragraphs 1-5), or constitute obvious variations in parameters which are routinely modified in the art and utilizing known reagents (e.g. adjusting the pH value, using adding cis-3-hydroxyproline as an internal

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standard, the o-phthalaldehyde reagent and azo dyes such as dabsyl chloride (claims 11-12 and 15) (see pg. 259, paragraphs 1-5 and pg. 262, paragraph 2)). Total hydroxyproline was determined by comparing t-4-Hyp/c-4-Hyp of hydrolysates (pg. 260, paragraph 1).

Although, Sessa et al does not teach performing the instant process in sequential order, It would have been obvious to one of ordinary skill in the art to use equivalent reagents because they yield equivalent results as that of the instant claimed process. Absent evidence to the contrary, the detection of known hydroxyprolines utilizing known reagents in the instant invention is viewed as routine optimization of the prior art method as described by Sessa et al especially since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. In re Stevens, 101 USPQ 284 (CCPA 1954). With respect to using cis-3-hydroxyproline as an internal standard, as recited in claim 15, it only requires routine skill in the art to use as an internal standard or control a modified form or derivative of hydroxyprolines since it is within the general skill of a worker in the art to select a known material on the basis of its suitability for intended use.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sessa et al (Journal of chromatography, 382(1986) 258-263) in view of Zuk et al (USP#4,281,061).

The teachings of Sessa et al are set forth above in differ from the instant claims in not teaching a kit.

However, Zuk et al teaches that as a matter of convenience the reagents of an assay can be provided as kits where the reagents are in predetermined ratios so as to substantially optimize the sensitivity of the assay in the range of interest (column 22, lines 63-66).

It would have been obvious to one of ordinary skill in the art to perform the method of quantifying hydroxyprolines and its derivatives as taught by Sessa et al. and using known reagents and formatting them into a kit for convenience as taught by Zuk et al to enhance sensitivity of the instant method.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Linblad et al. teaches a method for quantitation of hydroxyproline isomers in acid hydrolysates by high performance liquid chromatography (Analytical Biochemistry 138, 390-395 (1984)).

B. Bellon et al. teaches a method for further improvement of the fluorometric assay for hydroxyproline (J. of Chromatography, 278 (1983) 167-172).

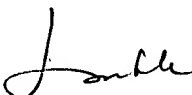
14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
March 24, 2003


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/24/03